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510(k) Summary

Proprietary Name: MITRAFLEX® Pigmented Wound Dressing

Common Name: Dressing

Classification: Unclassified

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Description:

MITRAFLEX Pigmented Wound Dressings are sterile, absorptive dressings.

MITRAFLEX combines the moist wound environment properties of film dressings with the absorptive qualities of traditional therapies in a structure which is both adhesive and conformable.

MITRAFLEX dressings are constructed of three layers, each specifically engineered to give MITRAFLEX its unique blend of "ease of use" features while providing a microenvironment conducive to moist wound healing.

The wound contact surface of MITRAFLEX is a porous adhesive which facilitates ease of application to the wound site. A second layer consisting of a microporous polyurethane membrane absorbs and acts as a reservoir for wound exudate. This layer is also moisture vapor permeable which facilitates the reduction of exudate while maintaining a moist environment to promote optimal wound repair. MITRAFLEX is impermeable to microorganisms and liquids.

MITRAFLEX Pigmented Wound Dressings are intended for use in the management of:

Venous stasis ulcers	Partial-thickness wounds
Diabetic ulcers	Superficial burns
Pressure sores	Abrasions and lacerations
Donor sites	Full-thickness wounds
Blisters	Skin tears
Incisions	Dermal lesions
Severe sunburn	Minor chemical burns
Poison Ivy	Thermal burns
Dermabrasions and other dermatologic procedures	
Facelifts and other plastic surgery procedures (e.g. laser resurfacing)	

MITRAFLEX Pigmented Wound Dressings are substantially equivalent to MITRAFLEX Wound Dressings, Wet-Stick, and MITRAFLEX Wound Dressings. These devices are all self-adhesive wound dressings which provide a degree of absorption and breathability. They are all intended for use in the management of a wide variety of dermal lesions and injuries.

MITRAFLEX Pigmented Wound Dressings have been shown in laboratory tests to be nontoxic, nonirritating, and nonsensitizing.